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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,954	07/12/2001	Michael E. Garst	17095CIPCON(AP)	3028

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EXAMINER	
FAY, ZOHREH A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 02/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/903,954	Applicant(s) GARST, MICHAEL E.	
	Examiner Zohreh Fay	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-7 and 14-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 14-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claims 1-7 and 14-27 are presented for examination.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex Parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) The quantity of experimentation,

2) The amount of direction or guidance provided,

3) The presence of absence of working examples,

4) The nature of the invention,

5) The state of the prior art,

6) The relative skill of those in the art,

7) The predictability of the art, and

8) The breadth of the claims.

Applicant fails to set forth the criteria that define "preventing of optic nerve" and "protection of the retinal ganglion cells". Additionally, applicant fails to provide information allowing the skilled artisan ascertain the "prevention" and "protection" without undue experimentation. There are no working examples in the instant specification to demonstrate the ability of the claimed combination in "preventing of optic nerve" or the "protection of retinal ganglion cells". One skilled in the art would not be able to determine the ability of the claimed combination, in achieving such actions, without undue experimentation. Applicant fails to provide information sufficient to practice the invention absent undue experimentation.

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 4, 6,7,14, 15, 17,19, 20, 21, 22, 24, 26 and 27 are rejected under 35 U.S.C. 102 (e) as being anticipated by Klimko et al. (U.S. Patent 6,184,250). Klimko et al. Teach the use of the claimed prostaglandins in combination with the claimed alpha-adrenergic agent, brimonidine for the treatment of glaucoma. Such use would

inherently prevent degeneration of optic nerve and would protect the retinal ganglion cells of a mammal.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gluchowiski (U.S. Patent 5, 091,528) and Bito (U.S. Patent 4,599,353).

Gluchowiski teaches the use of the claimed alpha-adrenergic agents for the treatment of glaucoma. See page 2, lines 19-28. Bito teaches the use of the claimed prostaglandin's for the treatment of glaucoma. See claims 1-10. The primary reference differs from the claimed invention in the presence of a prostaglandin agent. It would have been obvious to a person skilled in the art to incorporate a prostaglandin agent into the composition of the primary reference, considering that Bito teaches the claimed prostaglandins have been previously used for the treatment of glaucoma.

One skilled in the art would have been motivated to combine the teachings of the above references, since they in combination relate to the use of the claimed alpha-adrenergic and prostaglandins for the treatment of glaucoma. The combination of ingredients being used for the same purpose is merely the additive effect of each individual component in the absence of evidence to the contrary. There is no evidence of record to demonstrate the lesser side effect of the claimed combination. Applicant has presented no evidence to establish the unexpected or unobvios nature of the

claimed invention, and as such, claims 1-7 and 14-20 are properly rejected under 35 U.S.C. 103.

Claims 21-27 are rejected under 35 U.S.C. 103 as being unpatentable over Yavitz and Woodward (U.S. Patent for the reasons set forth on pages 2 and 3 of the office action of August 19, 2001. Applicant alleges criticality to the protect optic nerve and retinal ganglion cells in a patient suffering from glaucoma. The allegation is not well taken, since the claimed language is not directed to glaucoma.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Fay whose telephone number is (703) 308-4604. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ZOHREH FAY
PRIMARY EXAMINER
GROUP 1200

Z.F
February 13, 2003